

1 The opinion in support of the decision being
2 entered today is not binding precedent of the board.

Paper 1

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5 Filed by:

6
7 Fred E. McKelvey
8 Senior Administrative Patent Judge
9 Mail Stop Interference
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Filed 23 February 2006

15 UNITED STATES PATENT AND TRADEMARK OFFICE

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18 BEFORE THE BOARD OF PATENT APPEALS
19 AND INTERFERENCES
20 (Senior Administrative Patent Judge McKelvey)
21

22
23 TSUGUNORI **NOTOMI** and TETSU HASE,

24 Junior Party
25 (Patent 6,410,278 B1),
26

27 v.
28

29 ELAZAR **RABBANI**, JANNIS G. STAVRIANOPOULOS,
30 JAMES J. DONEGAN, JACK COLEMAN and MARLEEN WALNER,
31

32 Senior Party
33 (Application 10/306,990).
34

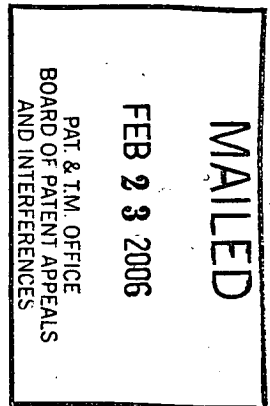
35
36 Patent Interference 105,427 (McK)
37 Technology Center 1600
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41 **DECLARATION**
42 **37 CFR § 41.203(b)**
43

44 **Part A.**
45 **Declaration of interference**

46 1. An interference is declared between the above-
47 identified parties. 35 U.S.C. § 135(a); 37 CFR § 41.203(b).

48 2. Details of the application, patent, count and
49 claims designated as corresponding or as not corresponding to the
50 count appear in Parts E and F of this DECLARATION.



1 **Part B.**
2 **Judge managing the interference**

3 Senior Administrative Patent Judge McKelvey has been
4 designated to manage the interference. 37 CFR § 41.104(a).

5 **Part C.**
6 **Standing order**
7

8 1. A Trial Division STANDING ORDER (3 Jan. 2006)
9 (Paper 2) accompanies this DECLARATION.

10 2. The STANDING ORDER applies to this interference,
11 including the provisions related to Electronic Filing. See
12 ¶ 105, pages 17-20.

13 **Part D.**
14 **Initial conference call and motions lists**
15

16 Conference call

17 1. A conference call to discuss the interference is
18 set for:

19 4:00 p.m. (1600 hours Eastern time) on Friday, 21 April 2006.

20 2. The board will initiate the call.
21

22 Motions lists

23 3. On or before:

24 noon (1200 hours Eastern time) Monday, 17 April 2006,
25 each party shall file, and on or before:

26 5:00 p.m. (1700 hours Eastern time) Monday, 17 April 2006,

1 each party shall serve, a notice stating the relief the party
2 requests, i.e, a motions list including motions the party seeks
3 authorization to file. 37 CFR § 41.120(a); STANDING ORDER ¶ 204,
4 (Paper 2, page 58).

5 4. The default procedure for filing and serving is
6 motions lists are to be filed before being served.

7 5. By filing before service, one party will not have
8 access to an opponent's motions list prior to filing the party's
9 motions list.

10 6. Nevertheless, the parties may mutually agree to
11 discuss and serve motions lists at any time prior to the date and
12 time motions lists are due.

13 7. The following shall be included in any motions
14 list:

15 (1) Proposed motion for benefit must identify the
16 application(s) for which benefit will be
17 sought.

18 (2) Proposed motion to attack benefit must
19 identify the application(s) being attacked.

20 (3) Proposed motion seeking judgment against an
21 opponent based on alleged unpatentability
22 must identify the statutory basis for the
23 alleged unpatentability and:

24 (a) if based on the prior art, identify the
25 prior art;

26 (b) if based on the first paragraph of
27 35 U.S.C. § 112, identify whether

1 written description, enablement and/or
2 best mode will be the basis of the
3 proposed motion;

4 (c) if based on no interference-in-fact,
5 briefly identify the reason;

6 (d) if based on an alleged failure to comply
7 with 35 U.S.C. § 135(b), briefly
8 identify the reason;

9 (e) if claim correspondence is involved,
10 identify any claim to be designated as
11 corresponding or not corresponding to
12 the count;

13 (f) if a new count is to be sought, identify
14 the new count.

15
16 8. A motions list shall not contain any "reservation
17 clause" whereby a party attempts to reserve a right to file
18 additional motions. Additional motions are those authorized by
19 the board consistent with the rules.

20 9. A sample schedule for taking action during the
21 motion phase appears as Form 2 (page 69) in the STANDING ORDER.

22 10. Counsel are encouraged to discuss the schedule
23 prior to the conference call and to agree, essentially consistent
24 with the sample schedule, on dates for taking action.

25 11. A typical motion period lasts approximately eight
26 (8) months.

27 12. Counsel should be prepared to justify any request
28 for a shorter or longer period.

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Part E.
Identification of the parties
Assignment of exhibit numbers
Initiating settlement discussions

Junior Party¹

Named inventors: Tsugunori Notomi, Japan
Tetsu Hase, Japan

Patent:² U.S. Patent 6,410,278 B1
issued 25 June 2002
based on application 09/530,061
filed 8 November 1999

Title: Process for synthesizing nucleic acid

Assignee: Eiken Kagaku Kabushiki Kaisha

¹ The junior party is the party with the latest accorded priority date as set out in this DECLARATION. 37 CFR § 41.201 (definition of "Senior party"); 37 CFR § 41.207(a)(1).

² The file is a paper file, not an Image File Wrapper (IFW) file. The first maintenance fee was timely paid on 16 December 2005 (see the enclosed USPTO fee records associated with the patent).

Senior Party³

Named inventors: Elazar Rabbani, New York
Jannis G. Stavrianopoulos, New York
James J. Donegan, New York
Jack Coleman, New York
Marleen Walner, New York

Application:⁴ Application 10/306,990,
filed 29 November 2002

Title: Novel methods for amplifying and
detecting nucleic acid sequences

Assignee: Enzo Life Sciences, Inc.
Enzo Biochem, Inc.

³ The senior party is the party with the earliest accorded priority date as set out in this DECLARATION. 37 CFR § 41.201 (definition of "Senior party"); 37 CFR § 41.207(a)(1).

⁴ The file is an Image File Wrapper (IFW), not a paper file.

1 **Assignment of exhibit numbers**
2 **37 CFR § 41.154(c) (1)**
3 -----

4 1. The senior party [Rabbani] is assigned exhibit
5 numbers:

6 **1001-1999**

7 2. The junior party [Notomi] is assigned exhibit
8 numbers:

9 **2001-2999**

10 3. If necessary, the board will use exhibit numbers:
11 **3001-3999**

12 **Initiating settlement discussions**
13 **STANDING ORDER ¶ 126.1 (Paper 2, pages 40-41)**

14 4. The senior party is responsible for initiating
15 settlement discussions.
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Part F.
Count and claims of the parties

Count 1

A method comprising:

- (A) providing a template having
 - (i) a 3' end portion comprising a first region located 3' terminal and a first complementary region which, under suitable conditions, anneal to one another to form a first loop,
 - (ii) a 5' end portion comprising a second region located 5' terminal and a second complementary region which, under suitable conditions, anneal to one another to form a second loop, and
 - (iii) a region connecting the 3' end portion and the 5' end portion;
- (B) extending the 3' terminal of the template to the 5' end of the template by means of a polymerase having strand displacement activity, when the first region and first complementary region are annealed to one another to form the first loop, to form a template extension which includes a third region located 3' terminal and a third complementary region that are substantially the same as the second complementary region and second region, respectively, and which, under suitable conditions, anneal to one another to form a third loop;
- (C) annealing to the first loop of the extended template an oligonucleotide primer comprising at the 3' terminal a nucleotide sequence complementary to at least a part of the first loop and at the 5' terminal a nucleotide sequence complementary to the first region of the template;

- 1 (D) extending the oligonucleotide primer along the
- 2 extended template, by means of a polymerase having
- 3 strand displacement activity, to form a new
- 4 template complementary to the template; and
- 5 (E) displacing the new template from the extended
- 6 template.

1 The claims of the parties are:

2 Notomi: 1-19

3 Rabbani: 216

4 The claims of the parties which correspond to Count 1 are:

6 Notomi: 11

7 Rabbani: 216

8 The claims of the parties which do not correspond to Count 1
9 are:⁵

11 Notomi: 1-10 and 12-19

12 Rabbani: None

13 The parties are accorded the following priority benefit for
14 Count 1:

16 Notomi:⁶ None

17 Rabbani: U.S. Patent 6,764,821⁷
18 issued 20 July 2004
19 based on application 09/439,594
20 filed 12 November 1999

21 U.S. Patent 6,743,605⁸
22 issued 01 June 2004
23 based on application 09/104,067
24 filed 24 June 1998
25
26

⁵ A claim which does not correspond to any count is not involved in the interference within the meaning of 35 U.S.C. § 135(a).

⁶ See Paper 4 for a discussion of possible benefit for Notomi.

⁷ The file is an Image File Wrapper (IFW), not a paper file.

⁸ The file is a paper file, not an Image File Wrapper (IFW) file.

Part G.
Heading to be used on papers

The following heading must be used on all papers filed in this interference. STANDING ORDER ¶ 106.1.1 (Paper 2, page 20).

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES
(Senior Administrative Patent Judge McKelvey)

TSUGUNORI **NOTOMI** and TETSU HASE,

Junior Party
(Patent 6,410,278 B1)
(Patent 6,974,670 B2),

v.

ELAZAR **RABBANI**, JANNIS G. STAVRIANOPOULOS,
JAMES J. DONEGAN, JACK COLEMAN and MARLEEN WALNER,

Senior Party
(Application 10/306,990).

Consolidated Interferences
Patent Interference 105,427 (McK)
Patent Interference 105,432 (McK)
Technology Center 1600

Part H.
Order form for requesting file copies

1. When requesting copies of files, a party shall use
STANDING ORDER Form 4 (page 71).

2. Use of Form 4 will expedite processing of any request.

3. A party should attach to any request for file copies a photocopy of Part E of this DECLARATION with a hand-drawn circle around the patents and applications for which a copy of a file wrapper is requested.

4. The parties are advised that a single order for files may be filled by the Office of Public Records at more than one time, particularly in a case like the present case where both IFW and paper files are involved. STANDING ORDER ¶ 109.2 (Paper 2, pages 25-27).

Part I.
Required paragraph for affidavits and declarations

1. The board has experienced cases in which a witness has belatedly advanced reasons why the witness would be unable to appear for cross examination at a reasonable time and place in the United States.

2. Consequently, to prevent surprise and hardship to the party relying on the testimony of the witness, the following paragraph must be included on the signature page of all affidavits (including declarations) filed in this case .

STANDING ORDER ¶ 157.2 (Paper 2, pages 52-53):

In signing this affidavit (declaration), I understand that the affidavit (declaration) will be filed as evidence in a contested case before the Board of Patent Appeals and Interferences of the United States Patent and Trademark Office. I also acknowledge that I may be subject to cross examination in the case and that cross examination will take place within the United States. If cross examination is required of me, I will appear for cross examination within the United States during the time allotted for cross examination.

/ss/Fred E. McKelvey
FRED E. McKELVEY,
Senior Administrative Patent Judge⁹

23 February 2006
Entered at: Alexandria, VA

9 As part of board efforts under the government Paperwork Elimination Act, signatures on papers originating from the board have been phased out in favor of a completely electronic record. Consequently, in this case papers originating at the board will not have signatures. The signature requirements for the parties have not changed. See, e.g., 37 CFR § 10.18 (2005).

1 Enc (there is no Form PTO-850):

2
3 STANDING ORDER (3 Jan. 2006) (Paper 2)
4 ORDER CONSOLIDATING INTERFERENCES (Paper 3)
5 ORDER DISCUSSING COUNT AND NOTOMI BENEFIT (Paper 4)
6 NOTICE OF REQUEST FOR ASSISTANCE ON TECHNOLOGY
7 and ORDER (Paper 5)
8 ORDER CANCELLING CLAIMS FROM RABBANI APPLICATION (Paper 6)
9

10 The following additional documents (1) are provided to
11 permit the parties to gain an early appreciation of the nature of
12 the interference and (2) do not constitute complete copies of any
13 file. They are not part of the record of the interference and
14 cannot be relied upon in the future merely because they are
15 enclosed with this DECLARATION. If a party would like any of the
16 following documents considered in the interference, the party
17 should make the document an exhibit and offer the exhibit in
18 evidence.
19

20 Copy U.S. Patent 6,410,278 B1
21 Copy U.S. Patent 6,974,670 B2
22 Copy of claims of application 10/306,990 before cancellation
23 of Rabbani claims 146-215, 217-234 and 238-274
24 Copy of USPTO maintenance fee payment
25 U.S. Patent 6,410,278 B1
26 Bibliographic data

1 cc (via overnight delivery):
2
3 Attorney for Notomi
4 (real party in interest
5 Eiken Kagaku Kabushiki Kaisha):
6
7 Michael L. Goldman, Esq
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12
13 Tel: 716-263-1000 (main)
14 Fax: 716-263-1800
15 Email: None
16
17 Attorney for Rabbani
18 (real party in interest
19 Enzo Life Sciences, Inc. and
20 Enzo Biochem, Inc.):
21
22 Ronald C. Fedus, Esq.
23 ENZO BIOCHEM, INC.
24 527 Madison Avenue (9th Floor)
25 New York, NY 10022
26
27 Tel: 212-583-0100
28 Fax: 212-583-1050
29 Email: None

INTERFERENCE DIGEST

Interference No. 105,427

Paper No. 22

Name: Tsugunori Notomi, et al.

Serial No.: 09/530,061

Patent No. 6,410,278, granted 06/25/02

Title: Process for synthesizing nucleic acid

Filed: 09/01/00

Interference with Rabbani et al.

DECISION ON MOTIONS

Administrative Patent Judge, _____ Dated, _____

FINAL DECISION

Board of Patent Appeals and Interferences, _____ Dated, _____

Court, _____ Dated, _____

REMARKS

This should be placed in each application or patent involved in interference in addition to the interference letters.